Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference A31324M	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP03/07121	International filing date (*day/month/year*) 05 June 2003 (05.06.03)	Priority date (*day/month/year*) 10 June 2002 (10.06.02)
International Patent Classification (IPC) or national classification and IPC A61K 31/167, 31/18, 31/381, 31/40, 31/404, 31/4164, 31/421, 31/422, 31/426, 31/437, 31/4402, 31/445, 31/451, 31/455, 31/47, 31/505, 31/498, 31/5375, 31/609, 31/616, A61P 35/00, 35/02, 35/04		
Applicant	INSTITUTE OF MEDICINAL MOLECULAR DESIGN. INC.	

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 05 June 2003 (05.06.03)	Date of completion of this report 13 November 2003 (13.11.2003)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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International application No.
PCT/JP03/07121

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1- a part of 11

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-11 are so unclear that no meaningful opinion could be formed *(specify)*:

The effective components of the drug compositions of the inventions of claims 1 through 11 include a great variety of compounds within a very wide range, and a complete search relating to all those compounds is difficult to conduct. On the other hand, only a tiny fraction of the effective components of the drug compositions of the inventions of claims 1 through 11 were supported by the specification, as defined by the PCT Article 6, or disclosed in the specification, as defined by the PCT Article 5.

Therefore, claims 1 through 11 and the specification do not meet the prescribed requirements to a degree enabling a meaningful international search.

Accordingly, in the previous international search report, the search of prior art documents was conducted, within a reasonable burden range, based on the compounds specifically described in the specification with respect to the inventions of claims 1 to 11. For this reason, the international preliminary examination was conducted within this search range.

☒ the claims, or said claims Nos. 1-11 are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1-a part of 11.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	8, 9	YES
	Claims	1-7, 10, 11	NO
Inventive step (IS)	Claims		YES
	Claims	1-11	NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

2. Citations and explanations

Document 1: WO, 99/65449, A2 (Smithkline Beecham Corporation), 23 December, 1999.
Document 2: WO, 99/55663, A1 (Vertex Pharmaceuticals Incorporated), 04 November, 1999.
Document 3: WO, 01/98290, A2 (Pharmacia & Upjohn S.P.A.), 27 December, 2001.

<Based on document 1>
The inventions of claims 1-5, 7 do not appear to possess novelty or involve an inventive step based on document 1 cited in the ISR.

Document 1 describes that the compound (HO)(R_A)Ph-CONH-Ph(R_B) represented by Formula I demonstrates an efficacious effect against cancer.
Changing some of the substitution groups in the compound of Formula I within a range of analogs with the object of providing compounds that are similarly effective against cancer could have been easily arrived at by a person skilled in the art.

<Based on document 2>
The inventions of claims 1-4, 6, 7 do not appear to possess novelty or involve an inventive step based on document 2 cited in the ISR. Further, the inventions of claims 8 and 9 do not appear to involve an inventive step based on the same document 2.

Document 2 describes that the compound represented by the formula (hydroxynaphthalene ring)-CONH-(Ph substituted with CF_3 or the like) is effective as an antitumor agent.
Changing some of the substitution groups within a range of analogs with the object of providing compounds that are similarly effective as antitumor agents could have been easily arrived at by a person skilled in the art.

<Based on document 3>
The inventions of claims 1-6, 10, and 11 do not appear to possess novelty or involve an inventive step based on document 2 cited in the ISR.

Document 3 describes that the compound represented by the formula (HO)Ph-CONH-(substituted heteroaryl) is effective as an antitumor agent.
Changing some of the substitution groups within a range of analogs with the object of providing compounds that are similarly effective as antitumor agents could have been easily arrived at by a person skilled in the art.

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
WO 02/49632 A1 (Institute of Medicinal Molecular Design Inc.) [E, X]	27.06.02	18.12.01	18.12.00
WO 02/076918 A1 (Suntory Ltd.) [E, X]	03.10.02	27.03.02	27.03.01

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*